



10 Rec'd

09 MAY 2001

4068-0002-0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
FRANCIS VANDERBIST ET AL : EXAMINER: KRATZ, C. AND  
SERIAL NO: 09/424,247 : SMITH, L.  
FILED: NOVEMBER 30, 1999 : GROUP ART UNIT: PCT LEGAL OFFICE  
FOR: DRY POWDER INHALER :  
EXCIPIENT, PROCESS FOR ITS  
PREPARATION AND  
PHARMACEUTICAL COMPOSITIONS  
CONTAINING IT

REQUEST FOR RECONSIDERATION  
OF DECISION ON REQUEST FOR  
RECONSIDERATION OF PETITION TO  
ACCEPT DECLARATION UNDER 37 CFR 1.47(a)

ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

SIR:

Responsive to the Decision on Request for Reconsideration of Petition To Accept  
Declaration under 37 C.F.R. §1.47(a), reconsideration is respectfully requested in view of the  
following further facts.

STATEMENT OF FACTS

1) In the Decision of November 29, 2000, it is stated that MPEP §409.03(d) requires  
that a bona fide attempt be made to present a copy of the application papers and oath to the  
non-signing inventor for signature; and

2) Also, the Decision states that a conclusion under 37 C.F.R. §1.47, that a non-signing inventor's conduct constitutes a refusal to sign, must be supported by all facts upon which the conclusion is based in an affidavit or declaration.

In reply, the following is noted:

3) On March 20, 2001, Applicants' attorneys forwarded, by certified mail, a copy of application S.N. 09/424,247, filed in the U.S. Patent Office on November 30, 1999, to Mr. Paul Maes, a co-inventor for this application, and a Declaration form for his execution (copy enclosed as attachment 1);

4) On March 26, 2001, Applicants' attorneys received a reply from Mr. Maes, wherein he states that he has no knowledge of the U.S. application filing, which appears to contradict his indication of receipt of 1 (copy enclosed as attachment 2);

5) On March 28, 2001, Applicants' attorneys forwarded by facsimile a further request to Mr. Paul Maes to execute the Declaration forwarded to him with a copy of the application on March 20, 2001 (copy enclosed as attachment 3);

6) On March 28, 2001, Applicants' attorneys received a reply by facsimile from Mr. Paul Maes indicating that the priority document for PCT/BE98/00064 is not a "French" application, but rather "European" 97870065.6 (copy enclosed as attachment 4);

7) On March 29, 2001, Applicants' attorneys forwarded, by facsimile and certified mail, a corrected Declaration for execution, as well as copies of the petition documents originally filed in the U.S. Patent Office for revival of the application (copy enclosed as attachment 5);

8) On March 30, 2001, Applicants' attorneys received a reply by facsimile from Mr. Paul Maes, as apparently dictated to Shannon Walker in Mr. Maes' absence, wherein he

continues to refuse to execute the Declaration in his possession (copy enclosed as attachment 6);

9) On April 3, 2001, Applicants' attorneys received a facsimile from Galephar P.R. Inc., providing both a copy of a French Assignment (with English translation) executed by Mr. Paul Maes on May 7, 1997, as well as a description provided by Francis Vanderbist and Phillippe Baudier, two co-inventors, regarding the contributions of each of the three named co-inventors to the work leading up to the present invention (copies enclosed as attachment 7);

10) On April 6, 2001, Applicants' attorneys received a facsimile from Mr. Paul Maes, with a copied e-mail attachment in French, from Mr. Marc Isgour. The facsimile from Mr. Maes clearly indicates his unwillingness to execute the Declaration in his possession (copies enclosed at attachment 8);

11) On April 11, 2001, Applicants' attorneys forwarded a clarifying reply to Mr. Maes, again, requesting that he execute the Declaration in his possession (copy enclosed as attachment 9);

12) On April 19, 2001, Applicants' attorneys forwarded yet another facsimile request and reminder to execute the Declaration in his possession and to retain the same to Applicants' attorneys for filing in the U.S. Patent Office (copy enclosed as attachment 10);

13) On April 20, 2001, Applicants' attorneys received a facsimile from Shannon Walker, acknowledging receipt of the facsimile of April 19, 2001 (item 12) above), but indicating that Mr. Maes was "out of the office" until April 23, 2001 (copy enclosed as attachment 11);

14) On April 27, 2001, Applicants' attorneys received a facsimile reply from Mr. Maes, wherein Mr. Maes appears to acknowledge that he is a co-inventor and states that "I

never said I wouldn't sign the Declaration." Although Mr. Maes alleges an "attempt to potentially remove my name from one of my inventions," he appears to ignore the many weeks of attempts by Applicants' attorneys to do, in fact, just the opposite, i.e., obtain his name on the Declaration for this application inasmuch as he appears to be a co-inventor for this application (see item 9) above) (copy enclosed as attachment 12);

15) On May 10, 2001, Applicants' attorneys received a facsimile from Mr. Maes, who, while still refusing to sign the Declaration for this application, insists that he "did not close the door to a fair arrangement about the proceeding" (copy enclosed as attachment 13);

16) On May 11, 2001, Applicants' attorneys forwarded a clarifying facsimile with yet a further plea for Mr. Maes to execute the Declaration for this application (copy enclosed as attachment 14); and

17) On May 25, 2001, Applicants' attorneys received a facsimile from Mr. Maes, wherein Mr. Maes indicates, again, that he has "not closed the door to concluding this situation" but provides no executed Declaration (copy enclosed as attachment 15).

18) No further correspondence has occurred.

#### REQUEST FOR RECONSIDERATION

From the above correspondence, it may be readily appreciated that Mr. Maes received by certified mail a copy of this application and a Declaration for his execution. Thus, MPEP §409.03(d) has been satisfied. Moreover, at his request, a corrected Declaration was further provided for his execution.

Yet, despite two (2) months of correspondence -- after his receipt of the corrected Declaration for his execution -- Mr. Maes has shown no interest or willingness to execute this Declaration. In fact, his actions amount to a refusal to execute this Declaration. In view of

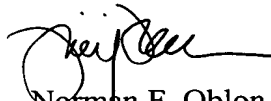
this demonstrated recalcitrance, it is respectfully submitted that Mr. Maes' conduct -- as evidenced by the attached correspondence -- constitutes a refusal to sign the Declaration under 37 C.F.R. §1.47.

Accordingly, Applicants respectfully urge that this application be accepted.

Favorable consideration is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



Norman F. Oblon  
Attorney of Record  
Registration No. 24,618

William E. Beaumont  
Registration No. 30,996



**22850**

PH: (703) 413-3000  
FX: (703) 413-2220  
WEB\la\pae  
I:\atty\WEB\40680002-request.wpd



10 Rec'd

09 MAY 2001

## ATTACHMENT 1



ATTORNEYS AT LAW

NORMAN F. OBLON  
(703) 413-3000  
NOBLON@OBLON.COMWILLIAM E. BEAUMONT  
(703) 413-3000  
WBEAUMONT@OBLON.COMMarch 20, 2001  
**VIA CERTIFIED MAIL**  
7000 1670 0002 9647 0647Biovail Technologies Ltd.  
3701 Concorde Parkway  
Chantilly, VA 20151

ATTENTION: Mr. Paul Maes

RE: U.S. Application Serial No. 09/424,247  
Your Ref. DPI PATENT TO REVIVE  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Enclosed herewith is a copy of a patent application filed in the U.S. Patent Office on November 30, 1999.

Since you are one of the listed co-inventors the invention described in this application, it is necessary that we obtain your signature (with the date) on the attached Declaration form. Please complete the address/residence portion of the form.

Please read the application and, thereafter, execute the Declaration. Thereafter, please return the executed Declaration (directed to my attention) to our office by facsimile. Our facsimile number is 703-413-2220. I would appreciate receiving the executed Declaration by

March 29, 2001.

With best regards,

Very truly yours,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

William E. Beaumont

WEB/pae

Enclosures: Application As Filed  
Declaration (for execution)

Monday, March 26, 2001 7:00 PM

Paul Maes 703-995-2223

p.01



10 h... 09 MAY 2001

Attention: **Mr. William Beaumont**

Date: 3/26/01

Company: Oblon, Spivak, McClelland, Maier &

Number of Pages: 2

Fax Number: 97034132220

Voice Number: 97034133000

**ATTACHMENT 2**

From: **Paul Maes**

Company: Biovail

Fax Number: 703-995-2223

Voice Number: 703-995-2355

Subject: US Application Serial No. 09/424,247 DPI; your ref. 4068-002-0

**Comments:**

Dear Mr Beaumont,

I received your certified mail concerning the above mentioned patent.

Please Find My request here attached,

Best Regards,

Paul Maes



Chantilly, Monday, March 26, 2001

US Application Serial No. 09/424,247 DPI; your ref. 4068-002-0  
Your letter dated March 20<sup>th</sup> 2001

*Caren*  
*(C.) B. Beaumont*  
**RECEIVED**  
MAR 27 2001

Dear Mr. Beaumont,

OBLON, SPIVAK, McCLELLAND  
MAIER & NEUSTADT, P.C.

I received your certified mail concerning the above-mentioned patent.

I understand that you may have filed a PCT application at the USPTO.

I'm aware of the Document citing prior art under WIPO 98/50015 (originated from PCT/BE98/00064 citing my name as an inventor amongst other and Pharylse Luxembourg as an assignee).

I do not have knowledge of the US filing (despite requests to Mr. Baudier), nor do I have knowledge of the French NR. 97870065.6.

Could you please send me all the missing information; Copy of the French Application, all relevant courier with the US Patent and Trademark Office ?

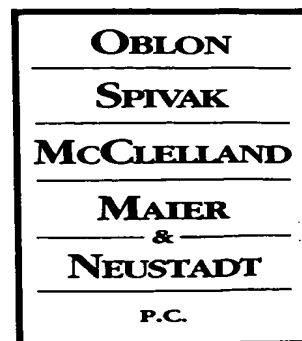
Thank you for your collaboration,

  
Paul Maes  
Vice President Pharmaceuticals





SENT BY FAX	
NO. OF PAGES	2
FAX #	703-995-2223



ATTORNEYS AT LAW

NORMAN F. OBLON  
(703) 413-3000

NOBLON@OBLON.COM

WILLIAM E. BEAUMONT  
(703) 413-3000  
WBEAUMONT@OBLON.COM

March 28, 2001

Mr. Paul Maes  
BIOVAIL Technologies Ltd  
3701 Concorde Parkway  
Chantilly, VA 20151

### ATTACHMENT 3

RE: U.S. Application Serial No. 09/424,247  
Your Ref. DPI PATENT TO REVIVE  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Thank you for your facsimile of March 26, 2001.

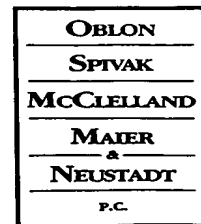
We confirm that international application PCT/BE 98/00064 was filed on May 7, 1998, claiming priority to EP 97870065.6 filed on May 7, 1997.

We also confirm that on November 30, 1999, a transmittal letter was filed in the U.S. Patent Office for entry into the national stage in the United States accompanied by a petition to revive an unintentionally abandoned application. The petition was granted.

As you are a listed co-inventor, we must now obtain your signature (with date thereof) on the Declaration forwarded to you with a copy of the application as filed in the U.S. Patent Office.

Please advise us immediately, i.e. not later than 48 hours upon receipt of this letter, whether you will execute the Declaration forwarded to you or not.

If we do not receive a definitive reply from you within 48 hours from receipt, and certainly no later than the close of business on Monday, April 2, 2001, we will have no choice but to presume that you will not execute the Declaration.



Mr. Paul Maes  
BIOVAIL Technologies Ltd  
Your Ref. DPI PATENT TO REVIVE  
Our Ref. 4068-0002-0 PCT  
Page 2

We look forward to receiving your reply.

With best regards,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

William E. Beaumont

WEB/pae



ATTACHMENT 4



Chantilly, Monday, March 28, 2001

US Application Serial No. 09/424,247 DPI; your ref. 4068-002-0  
Your FAX dated March 28<sup>th</sup> 2001

*Chm*  
*W. Beaumont*  
**RECEIVED**  
MAR 29 2001

*WEB*  
*PAELL*  
*03.16.01*

Dear Mr. Beaumont,

OBLON, SPIVAK, McCLELLAND  
MAIER & NEUSTADT, P.C.

I received your FAX concerning the above-mentioned patent.

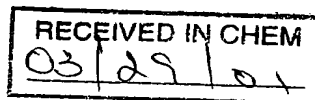
I would like to understand the discrepancies between your letter and the proposed declaration, namely the EP number on one hand and the "France" mentioned instead of EP at page 2.

I understand the pressure you have but you know that I cannot sign in good conscience any document without having reviewed and examined the implications of my signing. Therefore, until I have received all documents, including but not limited to the petition to revive from November 30, 1999 and the USPTO grant, I'm unable to fulfill your request.

As my office is located very close to your company it shouldn't be a problem for you to convey the required document in a short time.

Thank you for your collaboration,

Paul Maes  
Vice President Pharmaceuticals

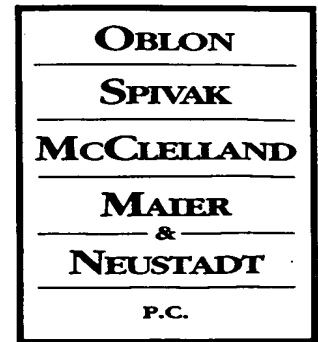


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Entered as General Mail	
Entered Case Specific	



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NO. OF PAGES <u>27</u>
FAX # <u>703-995-2223</u>

## ATTACHMENT 5



March 29, 2001  
**VIA FACSIMILE AND CERTIFIED MAIL**  
**7000 1670 0013 7147 8947**

Mr. Paul Maes  
BIOVAIL Technologies Ltd  
3701 Concorde Parkway  
Chantilly, VA 20151

**ATTORNEYS AT LAW**

NORMAN F. OBLON  
(703) 413-3000  
NOBLON@OBLON.COM  
WILLIAM E. BEAUMONT  
(703) 413-3000  
WBEAUMONT@OBLON.COM

RE: U.S. Application Serial No. 09/424,247  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Thank you for your facsimile of March 28, 2001.

First, the discrepancy noted was merely due to a typographical error. A corrected Declaration, referring to EP 97870065.6, is attached for your execution.

Second, also attached herewith is a copy of the documents filed in the U.S. Patent Office, including the petition to revive, based upon the information available at that time, and the grant thereof by the Patent Office.

As you now have copies of all documents requested, please advise us when we may expect to receive the executed Declaration.

With best regards,

Very truly yours,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

William E. Beaumont

WEB/pae

Enclosures: Declaration (for execution) (4 pgs), Decision (4 pgs)  
Copy of the Date-Stamped Filing Receipt  
Transmittal Letter (2 pgs), Declaration (as filed) (4 pgs)  
Request for Priority w/PCT/IB/304 (2 pgs), Petition to Revive (2 pgs)  
PCT/IB/308, Request for Consideration of Documents Cited (1 pg), International Search  
Report (3 pgs), Petition to Accept Declaration (2 pgs)



# Declaration and Power of Attorney for Patent Application

## Déclaration et Pouvoirs pour Demande de Brevet

### French Language Declaration

En tant l'inventeur nommé ci-après, je déclare par le présent acte que:

Mon domicile, mon adresse postale et ma nationalité sont ceux figurant ci-dessous à côté de mon nom.

Je crois être le premier inventeur original et unique (si un seul nom est mentionné ci-dessous), ou l'un des premiers co-inventeurs originaux (si plusieurs noms sont mentionnés ci-dessous) de l'objet revendiqué, pour lequel une demande de brevet a été déposée concernant l'invention intitulée

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

et dont la description est fournie ci-joint à moins

☐ ci-joint

☐ a été déposée le \_\_\_\_\_

sous le numéro de demande des Etats-Unis ou le  
numéro de demande international PCT

\_\_\_\_\_ et modifiée le

\_\_\_\_\_ (le cas échéant).

Je déclare par le présent acte avoir passé en revue et compris le contenu de la description ci-dessus, revendications comprises, telles que modifiées par toute modification dont il aura été fait référence ci-dessus.

Je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations.

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

DRY POWDER INHALER EXCIPIENT, PROCESS FOR  
ITS PREPARATION AND PHARMACEUTICAL  
COMPOSITIONS CONTAINING IT

the specification of which:

☐ is attached hereto.

☒ was filed on November 30, 1999

as United States Application Number or PCT  
International Application Number  
SN 09/424,247

\_\_\_\_\_ and was amended on

\_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

## French Language Declaration

Je revendique par le présent acte avoir la priorité étrangère, en vertu du Titre 35, § 119(a)-(d) ou § 365(b) du Code des Etats-Unis, sur toute demande étrangère de brevet ou certificat d'inventeur ou, en vertu du Titre 35, § 365(a) du même Code, sur toute demande internationale PCT désignant au moins un pays autre que les Etats-Unis et figurant ci-dessous et, en cochant la case, j'ai aussi indiqué ci-dessous toute demande étrangère de brevet, tout certificat d'inventeur ou toute demande internationale PCT ayant une date de dépôt précédant celle de la demande à propos de laquelle une priorité est revendiquée.

Prior Foreign Application(s)  
Demande(s) de brevet antérieure(s) dans un autre pays.

97870065.6      Europe  
(Number)      (Country)  
(Numéro)      (Pays)

\_\_\_\_\_  
(Number)      (Country)  
(Numéro)      (Pays)

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 119(e) du Code des Etats-Unis, de toute demande de brevet provisoire effectuée aux Etats-Unis et figurant ci-dessous.

\_\_\_\_\_  
(Application No.)      (Filing Date)  
(N° de demande)      (Date de dépôt)

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 120 du Code des Etats-Unis, de toute demande de brevet effectuée aux Etats-Unis, ou en vertu du Titre 35, § 365(c) du même Code, de toute demande internationale PCT désignant les Etats-Unis et figurant ci-dessous et, dans la mesure où l'objet de chacune des revendications de cette demande de brevet n'est pas divulgué dans la demande antérieure américaine ou internationale PCT, en vertu des dispositions du premier paragraphe du Titre 35, § 112 du Code des Etats-Unis, je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations, dont j'ai pu disposer entre la date de dépôt de la demande antérieure et la date de dépôt de la demande nationale ou internationale PCT de la présente demande:

PCT/BE98/00064      7 May 1998  
(Application No.)      (Filing Date)  
(N° de demande)      (Date de dépôt)

\_\_\_\_\_  
(Application No.)      (Filing Date)  
(N° de demande)      (Date de dépôt)

Je déclare par le présent acte que toute déclaration ci-incluse est, à ma connaissance, véridique et que toute déclaration formulée à partir de renseignements ou de suppositions est tenue pour véridique; et de plus, que toutes ces déclarations ont été formulées en sachant que toute fausse déclaration volontaire ou son équivalent est passible d'une amende ou d'une incarcération, ou des deux, en vertu de la Section 1001 du Titre 18 du Code des Etats-Unis, et que de telles déclarations volontairement fausses risquent de compromettre la validité de la demande de brevet ou du brevet délivré à partir de celle-ci.

I hereby claim foreign priority under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below, and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Priority claimed  
Droit de priorité  
revendiqué

7 May 1997  
(Day/Month/Year Filed)  
(Jour/Mois/Année de dépôt)

☐      ☐  
Yes      No  
Oui      Non

\_\_\_\_\_  
(Day/Month/Year Filed)  
(Jour/Mois/Année de dépôt)

☐      ☐  
Yes      No  
Oui      Non

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

\_\_\_\_\_  
(Application No.)      (Filing Date)  
(N° de demande)      (Date de dépôt)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Pending  
(Status) (patented, pending, abandoned)  
(Statut) (breveté, en cours d'examen, abandonné)

\_\_\_\_\_  
(Status) (patented, pending, abandoned)  
(Statut) (breveté, en cours d'examen, abandonné)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## French Language Declaration

**POUVOIRS:** En tant que l'inventeur cité, je désigne par la présente l'(les) avocat(s) et/ou agent(s) suivant(s) pour qu'ils poursuive(nt) la procédure de cette demande de brevet et traite(nt) toute affaire s'y rapportant avec l'Office des brevets et des marques: (mentionner le nom et le numéro d'enregistrement).

**POWER OF ATTORNEY:** As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: (list name and registration number)

Norman F. Oblon, Reg. No. 24,618; Marvin J. Spivak, Reg. No. 24,913; C. Irvin McClelland, Reg. No. 21,124; Gregory J. Maier, Reg. No. 25,599; Arthur I. Neustadt, Reg. No. 24,854; Richard D. Kelly, Reg. No. 27,757; James D. Hamilton, Reg. No. 28,421; Eckhard H. Kuesters, Reg. No. 28,870; Robert T. Pous, Reg. No. 29,099; Charles L. Gholz, Reg. No. 26,395; William E. Beaumont, Reg. No. 30,996; Jean-Paul Lavalleye, Reg. No. 31,451; Stephen G. Baxter, Reg. No. 32,884; Richard L. Treanor, Reg. No. 36,379; Steven P. Weihrouch, Reg. No. 32,829; John T. Goolkasian, Reg. No. 26,142; Richard L. Chinn, Reg. No. 34,305; Steven E. Lipman, Reg. No. 30,011; Carl E. Schlier, Reg. No. 34,426; James J. Kulbaski, Reg. No. 34,648; Richard A. Neifeld, Reg. No. 35,299; J. Derek Mason, Reg. No. 35,270; Surinder Sachar, Reg. No. 34,423; Christina M. Gadiano, Reg. No. 37,628; Jeffrey B. McIntyre, Reg. No. 36,867; William T. Enos, Reg. No. 33,128; Michael E. McCabe, Jr., Reg. No. 37,182; Bradley D. Lytle, Reg. No. 40,073; and Michael R. Casey, Reg. No. 40,294, with full powers of substitution and revocation.

Addresser toute correspondance à:

Send Correspondence to:

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
FOURTH FLOOR  
1755 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VIRGINIA 22202 U.S.A.

Adresser tout appel téléphonique à:  
(nom et numéro de téléphone)

Direct Telephone calls to: (name and telephone number)

(703) 413-3000

Nom complete de l'unique ou premier inventeur		Full name of sole or first inventor	
Signature de l'inventeur		Inventor's signature	
Date		Date	
Domicile		Residence	
Nationalité		Citizenship	
Adresse Postale		Post Office Address	
		B-1170 Brussels, BELGIUM	
Nom complete du second co-inventeur, le cas echeant		Full name of second joint inventor, if any	
Signature de l'inventeur		Second inventor's signature	
Date		Date	
Domicile		Residence	
Nationalité		Citizenship	
Adresse Postale		Post Office Address	

(Fournier les mêmes renseignements et la signature de tout co-inventeur supplémentaire.)

(Supply similar information and signature for third and subsequent joint inventors.)

## French Language Declaration

Nom complet du troisième co-inventeur, le cas échéant	Full name of third joint inventor, if any Philippe BAUDIER
Signature de l'inventeur <span style="float: right;">Date</span>	Third Inventor's signature <span style="float: right;">Date</span>
Domicile	Residence Waterloo, BELGIUM
Nationalité	Citizenship BELGIUM
Adresse Postale	Post Office Address Avenue, Blucher 10, B-1410
	Waterloo, BELGIUM

Nom complet du quatrième co-inventeur, le cas échéant	Full name of fourth joint inventor, if any
Signature de l'inventeur <span style="float: right;">Date</span>	Fourth Inventor's signature <span style="float: right;">Date</span>
Domicile	Residence
Nationalité	Citizenship
Adresse Postale	Post Office Address

Nom complet du cinquième co-inventeur, le cas échéant	Full name of fifth joint inventor, if any
Signature de l'inventeur <span style="float: right;">Date</span>	Fifth Inventor's signature <span style="float: right;">Date</span>
Domicile	Residence
Nationalité	Citizenship
Adresse Postale	Post Office Address

Nom complet du sixième co-inventeur, le cas échéant	Full name of sixth joint inventor, if any
Signature de l'inventeur <span style="float: right;">Date</span>	Sixth Inventor's signature <span style="float: right;">Date</span>
Domicile	Residence
Nationalité	Citizenship
Adresse Postale	Post Office Address

(Fournir les mêmes renseignements et la signature de tout co-inventeur supplémentaire.)

(Supply similar information and signature for third and subsequent joint inventors.)



Received at: 11:38AM, 3/30/2001

MAR-30-2001 11:27

BIOVAIL TECHNOLOGIES

P.01/02



ATTACHMENT 6

Biovail Technologies Ltd.  
3701 Concordo Parkway  
Chantilly, VA 20151

# CONFIDENTIAL

## facsimile transmittal

To: William E. Beaumont

Fax: 703-413-2220

From: Paul Maes c/o Shannon Walker

Date: 3/30/01

Re: Response letter

Pages: 2

CC:

☒ Urgent

☐ For Review

☐ Please Comment

☐ Please Reply

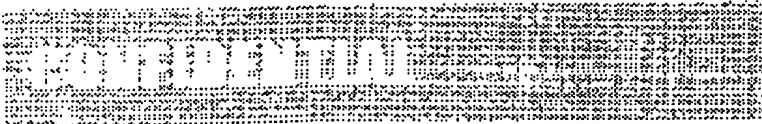
☐ Please Recycle



Please call me directly at (703) 995-2243 if you have any questions, or if I may further assist you.

Thank you,

Shannon Walker  
Assistant to Paul Maes



MAR-30-2001 11:28

BIOVAIL TECHNOLOGIES

P.02/02



**BIOVAIL**  
TECHNOLOGIES LTD.

March 30, 2001

Mr. William E. Beaumont  
Oblin Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

*W. Beaumont*  
**RECEIVED**  
MAR 30 2001

OBLIN, SPIVAK, MCCLELLAND  
MAIER & NEUSTADT, P.C.

*Dictated by Mr. Paul Maes to Shannon Walker in Mr. Maes absence*

Dear Mr. Beaumont,

Thank you for your fax dated March 30, 2001. I reviewed briefly the documents. As you appear to be in urgency of completing the file, but I note that there are a few missing documents for me to review before my completion of my assessments.

According to the letter, you listed Mr. Deboeck as an inventor and I don't remember having ever been involved with Mr. Deboeck in the development of DPI formulation. On the other hand, in this letter you made allegation of my refusal for a letter in October 1999. I don't remember this refusal. I would like a copy of your annex in order to check the reality of this allegation.

I didn't see a grant letter from the USPTO, but a dismissal letter. I would like to receive equally all the annex's from your second request for consideration you made on January 29, 2001.

Finally, according to his background and his total lack of know-how in pharmaceutical science, I have doubts about the inventorship of Mr. Baudair.

Looking forward to receiving ALL requested documents in this fax as they were previously in my fax dated March 28, 2001.

Thank you for your collaboration

*Shannon M. Walker per direction of Mr. Paul Maes*

Paul Maes  
Vice President, Pharmaceuticals

PM/smw

**BIOVAIL TECHNOLOGIES LTD.**  
3701 Concorde Parkway, Chantilly, Virginia 20151  
Tel: (703) 995-2400 Fax: (703) 995-2490

TOTAL P.02

**GALEPHAR P.R. Inc.**

## ATTACHMENT 7

**Fax**

To: Williams Beaumont From: A. H.  
Fax: 703 413 2220 Pages: 4 (including cover page)  
Phone: \_\_\_\_\_ Date: March 4. 01.  
Re: \_\_\_\_\_ CC: \_\_\_\_\_

☒ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

- If you do not receive this fax complete please call 787-713-0340.

*Dear will.*

• Here with the translation of the French assignment signed by Paul Hoes on May 7. 97.

• Draft declaration of the inventing Process by the 2 inventors. Please let me know if this is sufficient.

Regards

*A. H.*

Road 198 Km. 14.7 #100 Juncos Industrial Park,  
Juncos, Puerto Rico 00777-3873  
Tel. (787) 713-0340 - Fax (787) 713-0344  
E-mail: galephar@coqui.net

Beaumont

**RECEIVED**  
APR 03 2001 65

OBLON, SPIVAK, McCLELLAND  
MAIER & NEUSTADT, P.C.

## ASSIGNMENT

I the undersignee, Maes Paul, a Belgian citizen and Pharmacist – Director of R & D working for the corporation Laboratories SMB, Rue de la Pastorale 26 – 28 Molenbeek Saint Jean (Belgium) state with this letter, the following:

1. I surrender to Pharlyse, who accepts, all my rights concerning the invention "Dry Powder Inhaler Excipient, Process for it preparation and Pharmaceutical compositions containing it".
2. Authorizing this corporation to file in its own name a patent application for this invention in Europe and to prevail the property rights of this application for all patent applications.
3. Consider that this invention and all patents that may be originated from it are the property of the Pharlyse Corporation without any limitation.
4. I accept to furnish, to this corporation, all signatures and to accomplish in a general way, all necessary administrative formalities, which could be necessary for the completion of the filings of these patent applications.

This assignment is made in accordance with the agreement between the two parties.

Signed in Brussels

May 7, 1997

# Exhibit 1

## **ACTE DE CESSION**

Je soussigné MAES Paul, de nationalité belge, et exerçant au sein de la société LABORATOIRES S.M.B. Rue de la Pastorale 26-28 à MOLENBEEK ST JEAN (Belgique), la profession de Pharmacien - Directeur R&D déclare par la présente :

- 1° céder à la société PHARLYSE qui accepte tous mes droits sur l'invention relative à : "DRY POWDER INHALER EXCIPIENT, PROCESS FOR ITS PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING IT"
- 2° Autoriser dès lors celle-ci à déposer en son nom une demande de brevet pour cette invention en EUROPE et se prévaloir du droit de propriété que cette demande lui conférera pour tout dépôt de demandes de brevet
- 3° Considérer dès lors que cette invention et tous les brevets dont elle peut faire l'objet sont propriété de la société PHARLYSE sans restriction aucune.
- 4° Accepter de fournir à cette dernière toutes les signatures et accomplir d'une façon générale, toutes les formalités administratives qui pourraient être nécessaire pour le traitement du dossier de ces demandes de brevet.

Cette cession est effectuée suivant conditions convenues entre les parties.

  
Signé à Bruxelles

Le, 7 mai 1997

## **"DRY POWDER INHALER EXCIPIENT, PROCESS FOR IT PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING IT"**

### **INVENTION PROCESS**

The Patent (WO 98/50015) "Dry Powder Inhaler Excipient, Process for it preparation and Pharmaceutical compositions containing it" was invented by Francis Vanderbist, Paul Maes and Philippe Baudier.

Francis Vanderbist, Industrial Pharmacist employee of SMB and Project Manager had made the hypothesis that the Roller dried lactose could be of interest as a carrier for Dry Powder inhalation hoping that it could provide for increased stability of active drugs.

During a regular research and development meeting Francis Vanderbist reported this idea to Mr. Paul Maes, R & D Director and his direct supervisor at that time and to Mr. Philippe Baudier, Managing Director. The three present at that meeting concluded to go forward with the concept and decided to further meet on a regular basis and to assign to Francis Vanderbist the Laboratory work.

Brain storming meetings took place on a regular basis for the purpose of transforming the concept to useful medical application. Mr. Philippe Baudier principal collaboration was to select the useful areas of research by defining the active chemical entities of commercial and medical interest and by providing the necessary funding. Mr. Paul Maes, principal collaboration was to assure that the experiments performed were scientifically sound and that the work was performed on a timely basis.

After full collaboration on this project for about \_\_\_\_\_ years, a patent application was written in collaboration by the three inventors.

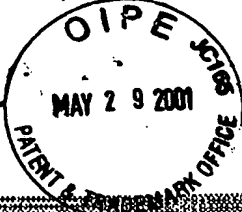
We, Francis Vanderbist and Philippe Baudier, declare that the patent "Dry Powder Inhaler Excipient, Process for it preparation and Pharmaceutical compositions containing it" listed in the PCT application PCT/BE98/00064 was originated from the collaborative work of the three inventors: Francis Vanderbist, Paul Maes and Philippe Baudier.

---

Francis Vanderbist

---

Philippe Baudier



Biovail Technologies Ltd.  
3701 Concord Parkway  
Chantilly, VA 20151

**CONFIDENTIAL****facsimile transmittal****ATTACHMENT 8**

To: William Beaumont Fax: 703-413-2220

From: Paul Maes c/o Shannon Walker Date: 4/6/01

Re: Further request to patent filing Pages: 3

CC:

☒ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle



Mr. Beaumont,

Attached please find a letter from Paul Maes further to his request of 30 March 2001. If you need assistance, please call me directly at (703) 995-2243.

Thank you,

Shannon Walker  
Assistant to Paul Maes

.....



April 6, 2001

Mr. William E. Beaumont  
Oblin Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

*W. Beaumont*  
**RECEIVED**  
APR 06 2001

OBLON, SPIVAK, McCLELLAND  
MAIER & NEUSTADT, P.C.  
*fr*

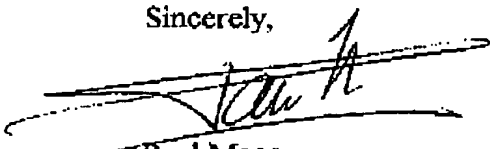
Dear Mr. Beaumont,

To date, I haven't heard from you since my last communication to you via fax and courier on March 30, 2001. This is surprising to me given the urgency you are in. I join for you information on e-mail from my lawyer in Belgium who hasn't heard from Mr. Baudier in more than one year. I propose my lawyer to get in contact with you so that you can sort out any legal issues surrounding the patent filing and other actions.

My lawyer's information is as follows:

Mr. Marc Isgour  
Avocat  
Avenue des Scarabées, 11  
1000 BRUXELLES  
Phone: 02/644.48.00  
Fax: 02/647.13.40

Sincerely,

  
Paul Maes  
Vice President, Pharmaceuticals

Cc: Mr. Marc Isgour

PM/smw



**Paul Maes**

---

**From:** Marc Isgour [marc.isgour@avocats.org]

**Sent:** Thursday, April 05, 2001 8:41 AM

**To:** pmaes@biovail-btl.com

**Cc:** Jean-Marc.Bricart@goffin-law.be

**Subject:** MAES / BREVETS

Cher Monsieur MAES,

Maître BRICART me transmet votre fax du 26 mars dernier auquel était annexé votre échange de correspondances avec Monsieur Beaumont.

Avez-vous eu une réaction à votre courrier du 26 mars 2001 ?

Souhaitez-vous que je fasse quelque chose à l'égard de Monsieur Baudier ?

Je n'ai plus de nouvelle de sa part ou de son avocat depuis plus d'un an.

Votre bien dévoué.

Marc Isgour

Avocat

Av nue des Scarabées, 11

1000 BRUXELLES

tél. 02/644.48.00

fax. 02/647.13.40

e-mail : [marc.isgour@avocats.org](mailto:marc.isgour@avocats.org)

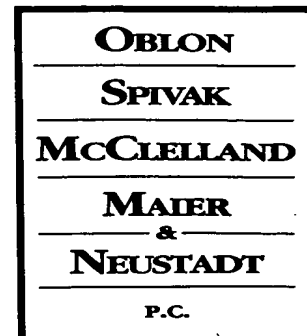
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NO. OF PAGES	<u>2</u>
FAX #	<u>703-995-2223</u>



April 11, 2001

**ATTACHMENT 9**

**VIA FACSIMILE**

Mr. Paul Maes  
BIOVAIL Technologies Ltd  
3701 Concorde Parkway  
Chantilly, VA 20151

ATTORNEYS AT LAW

NORMAN F. OBLON  
(703) 413-3000

NOBLON@OBLON.COM

WILLIAM E. BEAUMONT  
(703) 413-3000

WBEAUMONT@OBLON.COM

RE: U.S. Application Serial No. 09/424,247  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Thank you for your facsimile of April 6, 2001. Let me take this opportunity to clarify four points.

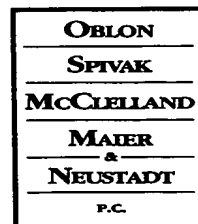
First, I do not now assert that Mr. Deboeck is an inventor. Any previous suggestion thereof was an error on my part. In fact, I presume that there are three inventors for this application as listed on the published cover sheet of the PCT application (PCT/BE98/00064), who are:

Francis Vanderbist  
Paul Maes  
Philippe Baudier

Second, any apparent "urgency" that you perceive on our part to obtain an executed Declaration for this case is merely due to the normal diligence required in order to complete the application file.

Third, I have no basis to question the status of Philippe Baudier as an inventor for this application and merely presume that he is a co-inventor based on published PCT/BE98/00064. See above. Moreover, I see no relevance in the fact that your attorney has not heard from Mr. Baudier in some time.

Fourth, since we forwarded the letter referred to in the second paragraph of your facsimile of March 30, 2001, to Biovail in Ontario based on our best knowledge at that time, we understand why you would have no knowledge of this letter. However, this is now irrelevant since we have your current address.



Mr. Paul Maes  
RE: U.S. Application Serial No. 09/424,247  
Our Ref. 4068-0002-0 PCT  
Page 2

The point of this exercise is to merely obtain an executed Declaration in order to complete the file for this application. See above. You have all necessary documents in your possession in order to do this. If you consider yourself to be an inventor, you have an interest in executing the Declaration previously forwarded to you, and returning the same to us for filing in the U.S. Patent Office.

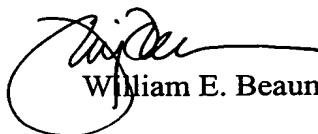
As you are, in fact, listed as a co-inventor for this case, it is necessary that you execute this Declaration. If you choose not to for whatever reason, we will have no choice but to proceed without you.

A prompt reply would be appreciated.

With best regards,

Very truly yours,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

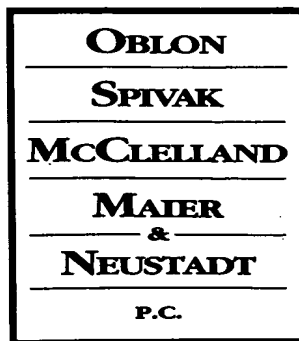


William E. Beaumont

WEB/pae



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NO. OF PAGES	<u>1</u>
FAX #	<u>703-995-2223</u> (w)



April 19, 2001

**ATTACHMENT 10**

Mr. Paul Maes  
BIOVAIL Technologies Ltd  
3701 Concorde Parkway  
Chantilly, VA 20151

**ATTORNEYS AT LAW**

NORMAN F. OBLON  
(703) 413-3000  
NOBLON@OBLON.COM  
WILLIAM E. BEAUMONT  
(703) 413-3000  
WBEAUMONT@OBLON.COM

RE: U.S. Application Serial No. 09/424,247  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Further to my letter of April 11, 2001, we continue to await the return of the executed Declaration for filing in the U.S. Patent Office.

As it appears, at least facially, from the published cover sheet of the PCT application (PCT/BE98/00064) that you are a co-inventor for this case, you have every reason to execute the Declaration now in your possession.

However, since you have chosen not to execute this Declaration, you have left us with no choice but to proceed without you.

With best regards,

Very truly yours,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

William E. Beaumont

WEB/pae



April 20, 2001

ATTACHMENT 11

Mr. William E. Beaumont  
Oblin Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

Dear Mr. Beaumont,

Please be aware that Mr. Maes has received your fax of last week. He is out of the office until Monday, April 23, 2001 and will review it then. Please call me if you have any questions, or if I may further assist you.

Sincerely,

*Shannon M. Walker*

Shannon M. Walker  
Assistant to Mr. Maes

PM/smw



Beaumont

April 27, 2001

**ATTACHMENT 12**

Mr. William E. Beaumont  
Oblin Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

Ref: U.S. Application Serial No. 09/424,247

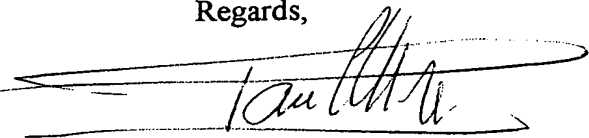
Dear Mr. Beaumont,

I have examined carefully all of the material you have sent me. I must admit, you confuse me. First, you send me partial information and seem to be in an emergency mode. Then I realized something – apparently something strange happened with one of your filings at the USPTO. On your letter of April 11<sup>th</sup> you claim that “now I do not pretend Mr. Deboeck is an inventor, and the emergency matters are not dramatic (“it is just normal diligence”) and finally in your fax dated April 19<sup>th</sup> you claim that I “have chosen not to execute the declaration”.

Mr. Beaumont, I never said that I was not involved in Pharmaceutical discovery for pulmonary devices and formulations. I never said that I wouldn't sign the declaration, but given your history with Mr. Baudier and “again” your apparent attempt to potentially remove my name from one of my inventions, I have difficulty in giving you any power of attorney.

Would you please, in order to be able to proceed in this case, copy me on all of your interventions about the above mentioned case.

Regards,

  
Paul Maes  
Vice President, Pharmaceuticals

Cc: Ivor

PM/smw

**RECEIVED**  
APR 30 2001  
OBLIN, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

**BIOVAIL TECHNOLOGIES LTD.**  
3701 Concorde Parkway, Chantilly, Virginia 20151  
Tel: (703) 995-2400 Fax: (703) 995-2490



ATTACHMENT 13

May 10, 2001

Mr. William E. Beaumont  
Oblon Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

W. Beaumont  
**RECEIVED**  
MAY 10 2001

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C. *14*

*Ref: U.S. Application Serial No. 09/424,247*

Dear Mr. Beaumont,

I am still awaiting an answer from you concerning my proposal made April 27, 2001.

As you are probably busy with other issues, just consider this letter a quick reminder. I believe you understand that I did not close the door to a fair arrangement about the proceeding. I just need to be certain that your client, Mr. Baudier, will not try again to jeopardize the legal validity of any patent related to one of my inventions.

I remain awaiting your response.

Regards,

*Paul Maes*  
Paul Maes  
Vice President, Pharmaceuticals

Cc: Ivor

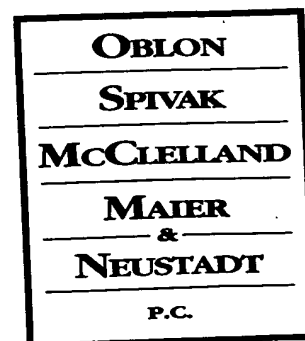
PM/smw

**BIOVAIL TECHNOLOGIES LTD.**  
3701 Concorde Parkway, Chantilly, Virginia 20151  
Tel: (703) 993-2400 Fax: (703) 993-2490

TOTAL P.02



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NO. OF PAGES	1
FAX #	703-995-2223



May 11, 2001

**ATTACHMENT 14**

Mr. Paul Maes  
BIOVAIL Technologies Ltd  
3701 Concorde Parkway  
Chantilly, VA 20151

ATTORNEYS AT LAW  
NORMAN F. OBLON  
(703) 413-3000  
NOBLON@OBLON.COM  
WILLIAM E. BEAUMONT  
(703) 413-3000  
WBEAUMONT@OBLON.COM

RE: U.S. Application Serial No. 09/424,247  
Our Ref. 4068-0002-0 PCT

Dear Mr. Maes:

Thank you for your facsimile of May 10, 2001.

We are still awaiting receipt of the executed Declaration from you. Further, I note the following.

First, our client is Galephar Pharmaceutical Research, Inc, not Mr. Baudier.

Second, I am unsure what you mean by a "fair arrangement about the proceeding". We are only asking for your signature (with date) on the Declaration in your possession. As you factually appear to be an inventor, you have an interest in executing the Declaration. I ask you, again, to forward the executed Declaration to us for filing in the U.S. Patent Office.

With best regards,

Very truly yours,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

William E. Beaumont

WEB/sej  
I:\atty\WEB\40680002-Maes.fx.wpd





**BIOVAIL**  
TECHNOLOGIES LTD.



May 25, 2001

## ATTACHMENT 15

Mr. William E. Beaumont  
Oblon Spivak McClelland Maier & Neustadt  
1755 Jefferson Davis Highway  
Fourth Floor  
Arlington, Virginia 22202

*Ref: U.S. Application Serial No. 09/424,247*

Dear Mr. Beaumont:

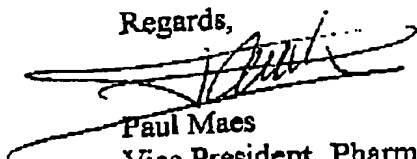
I am still awaiting an answer from you concerning my correspondence to you made on May 10, 2001. While I received a fax copy of your response, I have no original executed letter from you.

Your statement, "First, our client is Galephar Pharmaceutical Research, Inc., not Mr. Baudier," confirms my interest in having a complete copy of all the documents you send to and received from the USPTO. As a matter of fact, according to my information, Galephar PR has 2 shareholders representing more than 80% of the company. One is Philippe Baudier (major shareholder and executive), and the other being Arthur Deboeck (executive), whose name apparently was mentioned as an inventor in the previous failed attempt.

Once again, I remind you that I have not closed the door to concluding this situation, but you have to understand that I need your commitment to copy me on all documents concerning the patent filing #09/424,247 and/or any other related filing.

I remain awaiting your response.

Regards,



Paul Maes  
Vice President, Pharmaceuticals

Cc: Ivor

PM/smw

**BIOVAIL TECHNOLOGIES LTD.**  
3701 Concorde Parkway, Chantilly, Virginia 20151  
Tel: (703) 995-2400 Fax: (703) 995-2490